Attachment 5
510(K) Summary
Apex Er:YAG / IPL System

K 110304

APR - 8 2011

This 510(K) Summary of safety and effectiveness for the Apex Er:YAG / IPL System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: Address:	Sandstone Medical Technologies, LLC 105 Citation Court Birmingham, AL 35209
Contact Person: Telephone: Email:	Mark Rohrer 205-290-8251 – phone ssmed@bellsouth.net
Preparation Date:	January 31, 2011
Device Trade Name:	Apex Er:YAG / IPL System
Common Name: Classification Name:	ER:YAG laser and Intense Pulsed Light Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	MLT Erbium:YAG Laser System (K)032599 Apollo Mini IPL System (K)081219
Description of the Apex Er:YAG / IPL System:	The Apex system and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. There are 2 handpieces with the system. One is an Er:YAG laser which contains the laser cavity in the head of the handpiece. The second is an Intense Pulsed Light. These handpieces can be removed by the user and interchanged. The Er:YAG Laser energy produced within the device is delivered to the tissue in a wavelength of 2940nm. The Intense Pulsed Light wavelengths are 450nm – 1200nm The user activates laser and IPL emission by means of a footswitch.
Intended use of the Apex Er:YAG / IPL System:	The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery). The IPL Handpiece is indicated for use in skin types I-IV according to the Fitzpatrick Scale for the following indications: Hair Removal (650nm filter), Permanent hair reduction (650nm filter), Treatment of vascular lesions (510nm filter),Treatment of benign pigmented lesions (510 nm filter), Mild to Moderate inflammatory acne (450nm filter)

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510(K) Summary
Apex Er:YAG / IPL System

Performance Data: None

Results of Clinical Study: None

Summary of Technological Characteristics:

	Sandstone Medical Technologies LLC Apex Er:YAG / IPL System	Sandstone Medical Technologies LLC Apollo Mini IPL System
Light Source	**Pulsed Incoherent Light**	**Pulsed Incoherent Light**
Max Fluence	Up to 35J/cm^2	Up to 35J/cm^2
Wavelength	450 - 1200 nm	450 - 1200 nm
Spot Size	35 x 15 mm^2	35 x 15 mm^2
Pulse Width	Up to 200ms	Up to 200ms
Beam Delivery Stem	Light Guide	Light Guide

	Sandstone Medical Technologies LLC Apex Er:YAG / IPL System	Sandstone Medical Technologies LLC Er:YAG Laser
Wavelength	**2940nm**	**2940nm**
Max Power	2.4 W	2.4 W
Max Fluence	5J/cm2	5J/cm2
Pulse Width	300 µs	300 µs
Repetition Rate	Up to 10 pulse per second	Up to 10 pulse per second
Spot Size	1.5mm, 3mm, 6mm, 9mm	1.5mm, 3mm, 6mm, 9mm

Conclusion: The Apex Er:YAG / IPL is substantially equivalent to the MLT Erbium:YAG Laser System (K)032599 and to the Apollo Mini IPL System (K)081219. The Apex Er:YAG / IPL is substantially equivalent in terms of indication for use and technology based on technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sandstone Medical Technologies LLC
% Mr. Mark Rohrer
105 Citation Court
Birmingham, Alabama 35209

APR - 8 2011

Re: K110304
Trade/Device Name: Apex ER:YAG / IPL System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 31, 2011
Received: February 03, 2011

Dear Mr. Rohrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K ~~Pending~~ 110304

Device Name: Apex Er:YAG / IPL System

The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

The IPL Handpiece is indicated for use in skin types I-IV according to the Fitzpatrick Scale for the following indications:

Hair Removal
(650nm filter)
Permanent hair reduction
(650nm filter)
Treatment of vascular lesions
(510nm filter)
Treatment of benign pigmented lesions
(510 nm filter)
Mild to Moderate inflammatory acne
(450nm filter)

Prescription Use ___xx___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number 110304